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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,477	11/13/2000	Isabelle Preuilh	2365-23	4547

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ARLINGTON, VA 22203

EXAMINER
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COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/709,477	PREUILH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 7/17/2006, 7/19/2006 and 8/28/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31,32,36-42,44-46 and 51-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31,32,36-42,44-46 and 51-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

This office action is in response to the amendment and remarks submitted on August 28, 2006. Claims 31-32, 36-42, 44-46 and 51-67 are pending in the application and are being examined on the merits herein.

Applicant's arguments regarding the rejections of the claims have been fully considered but they are not persuasive.

The claims are rejected as set forth below.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 32, 37-42, 44-46, 51, 57-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,22,837 to William W. Cameron, issued February 2, 1988 in view of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology (of record.)

The instant claimed invention is directed to a composition comprising, in an aqueous medium an active principle selected from a corticoid or a retinoid, an anionic surfactant, an amphoteric surfactant and 0.1 to 25% of a propenetrating agent selected from volatile C1-C4 alcohols and glycol ethers.

Cameron teaches a medicated shampoo composition comprising 0.1-0.5% hydrocortisone, 20-35% detergent, 1-6% thickener, preservative and other ingredients, wherein the detergent can be combination of sodium lauryl sulfate (anionic surfactant) and cocoamidopropyl betaine (amphoteric surfactant.) Cameron further teaches that

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the medicated shampoo is suitable for the treatment of scalp disorders such as flaking, scaling, dandruff, seborrhea, eczema, psoriasis and others (see abstract and column 1, line 5 through column 6, line 35, in particular.) Cameron does not specifically teach the claimed propenetrating agents or the combination of anionic and amphoteric surfactants as recited in the claims.

Hirota teaches a composition for the scalp that is suitable for the treatment of conditions such as dandruff and scalp itching (see abstract, in particular.) Hirota teaches that the composition comprises a polyalkylene glycol monoalkyl ether of formula (I) (see abstract, in particular), such as diethylene glycol monoethyl ether (i.e. ethoxydiglycol as recited in claim 44), and that the component shows beneficial effects when provided in a hair care composition, such as the suppression of dandruff and itching as well as controlling the growth of bacterial flora and maintaining moisture on the scalp (see paragraphs 0008-0009, in particular.) Hirota teaches that an amount of the polyalkylene glycol can be from 0.1 to 5% by weight (see abstract, in particular), which meets the limitation as recited in the claim.

Hirota furthermore teaches that the treatment composition can be formulated with alcohols that are conventionally used in hair cosmetics, such as ethanol as recited in claim 44 (see paragraphs 0023-0024, in particular), and teaches that 10-90% of the ethanol can be provided, which range overlaps with that recited for the propenetrating agent amount recited in claim 1. Thus, Hirota teaches that a scalp treatment

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formulation can comprise the recited propenetrating agents of ethoxydiglycol and ethanol for the treatment of scalp disorders such as dandruff and itching.

The Handbook of Cosmetic Science and Technology teaches that amphoteric surfactants provide foam stabilization in combination with the ability to mitigate irritancy of other materials, such as primary surfactants and, in some cases, will modify product viscosity. They are taught as being compatible with anionic surfactants, wherein anionic surfactants are taught as the primary surfactants. See pages 220-224, in particular.

Accordingly it would have been obvious to one of ordinary skill in the art to provide the ethoxydiglycol of Hirota to the scalp treatment composition of Cameron, because Cameron teaches treating scalp conditions such as dandruff and other conditions associated with itching, such as psoriasis, and Hirota teaches that ethoxydiglycol provides benefits in the treatment of dandruff and itching. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ethoxydiglycol of Hirota in the composition of Cameron with the expectation of forming a scalp treatment composition suitable for the treatment of scalp disorders such as dandruff and psoriasis. It would furthermore have been obvious to provide the ethanol of Hirota in the composition of Cameron, because Hirota teaches that ethanol is an alcohol that is conventionally used as a carrier for hair treatment compositions.

It would furthermore have been obvious to one of ordinary skill in the art at the time the invention was made to provide the composition of Cameron and comprising both the anionic and amphoteric surfactants as claimed because of the expectation of achieving a composition that is more stable and that decreases irritation, as taught by the Handbook of Cosmetic Science and Technology. Accordingly, claims 31-32, 37-42, 44-46 and 57-61 are obvious over the teachings of the references.

Furthermore, regarding the specific amount of the anionic and amphoteric surfactants provided, as recited in claims 1 and 64-65, it is noted that Cameron teaches that an amount of a detergent provided can be from 25-35% (see column 2, lines 55-70, in particular.) Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of anionic and/or amphoteric surfactant provided in the composition, according to the guidance provided by Cameron, Hirota and the Handbook of Cosmetic science and Technology, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

While the ratio of anionic to amphoteric surfactant, for example as recited in claims 51 and 66, is not specifically taught, and the specific amount of a propenetrating agent that is a volatile C1-C4 alcohol, is also not specifically taught, it is respectfully

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pointed out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Accordingly, claims 51 and 66 are obvious over the references.

The Examiner respectfully points out that the recitation "foaming" and "for washing and treating the hair and/or scalp" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hira*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Claim 55 is rejected under 35 U.S.C. 103(a) above as being unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 4,22,837 to William W. Cameron, issued February 2, 1988 and of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology, as applied to claims 31, 32, 37-42, 43-46, 51 and 57-66 above, and further in view of U.S. Patent No. 5,378,731 to Andrews et al, issued January 3, 1995.



Cameron, Hirota and the Handbook of Cosmetic Science and Technology are applied as discussed for claims 31, 32, 37-42, 43-46, 51 and 57-66 above, and teach the hair and/or scalp treatment composition as recited in the claims.

The references do not specifically teach that a pH of the composition is between 2 and 9, as recited in claim 55.

Andrews et al. teaches a medicated shampoo for disinfecting, cleansing, conditioning and moisturizing the hair (see abstract, in particular.) Andrews et al. exemplifies such medicated shampoos having a pH of from 3.6 to 3.8 (see column 11, lines 9-44, in particular), which meets the range limitation of claim 55.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the treatment shampoo of Cameron, Hirota and the Handbook with a pH of 3.6-3.8, as taught by Andrews et al, with the expectation of achieving a cosmetically acceptable formulation that is safe for application to the hair and scalp.

Claim 36 is rejected under 35 U.S.C. 103(a) above as being unpatentable over U.S. Patent No. 4,22,837 to William W. Cameron, issued February 2, 1988 and of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology, as applied to claims 31, 32, 37-

42, 43-46, 51 and 57-66 above, and further in view of U.S. Patent No. 5,998,395 to Albert M. Kligman, issued December 7, 1999.

Cameron, Hirota and The Handbook of Cosmetic Science and Technology are applied as discussed for claims 31, 32, 37-42, 43-46, 51 and 57-66, and teach the claimed hair and/or scalp treatment composition. The references do not teach the specific active principle as recited in 36 that is clobetasol 17-propionate.

Kligman teaches methods of treating inflammatory dermatosis (see abstract, in particular.) Disclosed are compositions comprising a combination of clobetasol propionate or triamcinolone acetonide or hydrocortisone and tretinoin, wherein the corticosteroid comprises 0.00001-3% of the composition. It is disclosed that these compounds work synergistically. The compositions are disclosed as taking on various forms, such as creams, dressings, gels, lotions, ointments or liquids. Further examples of suitable retinoids disclosed include retinyl palmitate and retinyl propionate. The retinoids can be natural or synthetic (see column 1, line 19 through column 12, line 20, in particular.)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the compounds taught by Kligman into the composition of the combined references because of the expectation of success in achieving a composition that exhibits a synergistic effect in treating chronic dermatosis,

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such as seborrheic dermatitis, atopic dermatitis, contact dermatitis, psoriasis, and others, and because it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claims 52-54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,22,837 to William W. Cameron, issued February 2, 1988 and of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology, as applied to claims 31, 32, 37-42, 43-46, 51 and 57-66 above, and further in view of U.S. Patent No. 5,661,118 to Cauwet et al, issued August 26, 1997.

Cameron, Hirato and The Handbook of Cosmetic Science and Technology are applied as discussed for claims 31, 32, 37-42, 43-46, 51 and 57-66 above, and teach the claimed composition for the treatment of the hair and/or scalp. The references do not teach the specific cationic polymers and ceramides as recited in claims 52-54 and 56.

Cauwet et al. teaches hair and skin washing and treatment compositions based on ceramide and/or glycosphingolipid and cationic polymers. The combination of cationic polymer and ceramide and/or glycosphingolipid provides synergistic detangling. Cationic polysaccharides are taught as cationic polymers. Disclosed is a composition

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comprising sodium lauryl ether sulphate, cocoylbetaine, ceramide A, and guard hydroxypropyltrimmonium chloride. Nonionic surfactants are disclosed as constituents that may be especially contained within the composition. Cationic polymers comprise 0.05-5% of the composition (see column 13, line 1 through column 20, line 65, in particular.)

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,722,837 to William W. Cameron, issued February 2, 1988 in view of JP 07-18946 to Osamu Hirota (machine translation), published July 25, 1995, in view of The Handbook of Cosmetic Science and Technology (of record), as applied to claims 31, 32, 37-42, 44-46, 51, 57-66 above, and further in view of U.S. Patent No. 5,998,395 to Albert M. Kligman, issued December 7, 1999, U.S. Patent No. 5,661,118 to Cauwet et al, issued August 26, 1997, and U.S. Patent No. 5,631,003 to Mueller et al, issued May 20, 1997.

Cameron, Hirota and the Handbook of Cosmetic Science and Technology are applied as discussed above, and teach a composition, such as a shampoo composition for application to the scalp, comprising treatment agents such as hydrocortisone in a carrier comprising ethanol and water, for the treatment of skin conditions such as dry skin, eczema and psoriasis.

It is furthermore noted that the references teach providing surfactants such as sodium lauryl ether sulphate (i.e. sodium laureth sulphate) and cocoyl betaine (see column 2, lines 55-70 of Cameron, in particular)

The references do not specifically teach providing citric acid, sodium citrate, polyquaternium 10 or clobetasol propionate, as recited in the claim.

Kligman teaches that it is known that inflammatory dermatoses, such as psoriasis, seborrheic dermatitis and other dermatoses, are treatable with corticosteroids, such as clobetasol propionate (see column 1-2, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the clobetasol propionate of Kligman as the active agent in a shampoo composition, and including the shampoo surfactants, water and ethanol, as taught by Cameron, Hirota and the Handbook, because Cameron, Hirota and the Handbook all teach that shampoos can be formulated for the treatment of scalp disorders such as psoriasis, eczema, seborrhea, etc, whereas Kligman teaches that clobetasol propionate is a corticosteroid capable of providing treatment of such conditions. Thus, one of ordinary skill in the art would have been motivated to provide the clobetasol propionate in a shampoo or scalp treatment carrier form, as taught by the references, with the expectation of providing a suitable active agent and carrier system for the treatment of the scalp conditions.

Kligman, Cameron, Hirota et al. and the Handbook do not specifically teach providing citric acid, sodium citrate or polyquaternium 10 in the shampoo/scalp treatment composition.

Cauwet et al. teaches a hair washing composition (shampoo) comprising surface active agents and polymers containing cationic groups (see abstract, in particular.) Cauwet et al. teaches that cellulosic polymers such as polyquaternium-10 can be advantageously provided in such hair washing compositions (see column 3, lines 40-70 and Example 14, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate the polyquaternium-10 of Cauwet et al. in the shampoo composition of Kligman, Cameron, Hirota et al. and the Handbook, because Kligman, Cameron, Hirota et al. and the Handbook teach a shampoo composition for the treatment of scalp conditions, and Cauwet et al. teaches that polyquaternium 10 is a cationic polymer that is advantageously added to shampoo compositions. Thus, one of ordinary skill in the art would have been motivated to include the polyquaternium-10 with the expectation of providing a suitable additive for the shampoo composition.

Cameron, Hirota et al, the Handbook, Kligman and Cauwet et al. do not specifically teach providing citric acid and sodium citrate in the composition. However, Cameron does teach that medicated shampoo compositions for the dermatological treatment can comprise pH adjusters (see column 2, lines 33-37, in particular)

Mueller et al. teaches that typical constituents of hair treatment preparations include pH regulators, such as a citric acid/sodium citrate buffer (see column 6, lines 35-40 and line 65, in particular.)

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the citric acid/sodium citrate buffer of Mueller et al. in the medicated shampoo/scalp treatment composition of Cameron, Hirota et al, the Handbook, Kligman and Cauwet et al, because Cameron teaches it is known to provide pH adjusters, and Mueller et al. teaches that citric acid/sodium citrate buffers are typical constituents of hair care treatment products. Thus, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the citric acid/sodium citrate buffer of Mueller et al. in the composition of Cameron, Hirota et al, the Handbook, Kligman and Cauwet et al, with the expectation of providing a pH adjustor suitable for a shampoo/scalp treatment composition. Accordingly, a composition that consists of the ingredients as recited in claim 67 is considered to be obvious over the teachings of the prior art.

Regarding the specific amounts of the components provided, as recited in the claim, it is noted that it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the ingredients provided in the composition, according to the guidance provided by Cameron, Hirota et al, the Handbook, Kligman, Cauwet et al. and Mueller, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

### ***Response to Arguments***

Applicant's arguments with respect to the rejections of the claims have been considered but are moot in view of the new grounds of rejection.

In particular, Applicants argue that the references do not teach the composition is capable of foaming. However, the Examiner notes that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).



***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

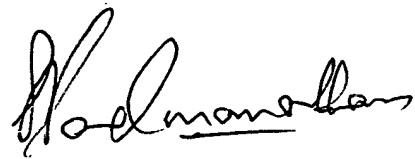
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', written in a cursive style.

**SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER**